

WHAT IS CLAIMED IS:

- 1.- An immediate-release fenofibrate composition comprising:

5 (a) an inert hydrosoluble carrier covered with at least one layer containing fenofibrate in a micronized form having a size less than 20 µm, a hydrophilic polymer and, optionally, a surfactant; said hydrophilic polymer making up at least 20% by weight of (a); and

10 (b) optionally one or several outer phase(s) or layer(s).

20 2.- The composition according to claim 1, in which a surfactant is present with fenofibrate and the hydrophilic polymer.

25 3.- The composition according to claim 1, in which the hydrophilic polymer is polyvinylpyrrolidone.

4.- The composition according to claim 2, in which fenofibrate and the surfactant are co-micronized.

25 5.- The composition according to claim 2, in which said surfactant is sodium laurylsulfate.

30 6.- The composition according to claim 1, in which the hydrophilic polymer is polyvinylpyrrolidone, and a surfactant is present with fenofibrate.

7.- The composition according to claim 6, in which fenofibrate and the surfactant are co-micronized.

35 8.- The composition according to claim 6, in which said surfactant is sodium laurylsulfate.

9.- The composition according to claim 1, in which the weight ratio fenofibrate/hydrophilic polymer is comprised between 1/10 and 4/1.

5 10.- The composition according to claim 6, in which the weight ratio fenofibrate/hydrophilic polymer is comprised between 1/10 and 4/1.

10 11.- The composition according to claim 1, in which the weight ratio fenofibrate/hydrophilic polymer is comprised between 1/2 and 2/1.

15 12.- The composition according to claim 6, in which the weight ratio fenofibrate/hydrophilic polymer is comprised between 1/2 and 2/1.

13.- The composition according to claim 1, in which, based on the weight of (a), said inert hydrosoluble carrier makes up from 10 to 80% by weight, said fenofibrate makes up from 5 to 50% by weight, said hydrophilic polymer makes up from 20 to 60% by weight, and said surfactant makes up from 0 to 10% by weight.

25 14.- The composition according to claim 1, in which, based on the weight of (a), said inert hydrosoluble carrier makes up from 20 to 50% by weight, said fenofibrate makes up from 20 to 45% by weight, said hydrophilic polymer makes up from 25 to 45% by weight, and said surfactant makes up from 0.1 to 3% by weight.

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15.- The composition according to claim 6, in which, based on the weight of (a), said inert hydrosoluble carrier makes up from 10 to 80% by weight, said fenofibrate makes up from 5 to 50% by weight, said hydrophilic polymer makes up from 20 to 60% by weight, and said surfactant makes up from 0 to 10% by weight.

16.- The composition according to claim 6, in which, based on the weight of (a), said inert hydrosoluble carrier makes up from 20 to 50% by weight, said fenofibrate makes up from 20 to 45% by weight, said 5 hydrophilic polymer makes up from 25 to 45% by weight, and said surfactant makes up from 0.1 to 3% by weight.

17.- The composition according to claim 1, in which the individual particle size of said inert hydrosoluble 10 carrier is comprised between 50 and 500 microns.

18.- An immediate-release fenofibrate composition comprising:

(a) an inert hydrosoluble carrier covered with at 15 least one layer containing fenofibrate in a micronized form having a size less than 20 μm , polyvinylpyrrolidone, and a surfactant; and

(b) optionally one or several outer phase(s) or 20 layer(s),

in which, based on the weight of (a), said inert hydrosoluble carrier makes up from 20 to 50% by weight, said fenofibrate makes up from 20 to 45% by weight, said polyvinylpyrrolidone makes up from 25 to 45% by weight, and said surfactant makes up from 0.1 to 3% by weight.

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19.- The composition according to claim 18, in which said surfactant is sodium laurylsulfate, which is co-micronized with fenofibrate.

30 20.- A composition comprising fenofibrate having a dissolution of at least 10% in 5 minutes, 20% in 10 minutes, 50% in 20 minutes and 75% in 30 minutes, as measured using the rotating blade method at 75 rpm according to the European Pharmacopoeia, in a dissolution 35 medium constituted by water with 2% by weight polysorbate 80 or with 0.025M sodium lauryl sulfate.

- 21.- The composition according to claim 1, under the form of a tablet.
- 22.- The composition according to claim 6, under the 5 form of a tablet.
- 23.- The composition according to claim 18, under the form of a tablet.
- 10 24.- The composition according to claim 20, under the form of a tablet.
- 25.- The composition according to claim 21 under the form of a tablet resulting from the compression of 15 elements (a) together with an outer phase.
- 20 26.- The composition according to claim 22 under the form of a tablet resulting from the compression of elements (a) together with an outer phase.
- 27.- The composition according to claim 23 under the form of a tablet resulting from the compression of elements (a) together with an outer phase.
- 25 28.- A method for preparing a composition according to claim 1, comprising the steps of:
(a) preparing a fenofibrate suspension in micronized form with a particle size below 20 µm, in a solution of hydrophilic polymer and, optionally surfactant;
30 (b) applying the suspension from step (a) to an inert hydrosoluble carrier;
(c) optionally, coating granules thus obtained with one or several phase(s) or layer(s).
- 35 29.- The method according to claim 28, in which step (b) is carried out in a fluidized-bed granulator.

30.- The method according to claim 28, comprising a step in which products obtained from step (b) or (c) are compressed.

5 31.- A suspension of fenofibrate in micronized form having a size less than 20 μm , in a solution of hydrophilic polymer and, optionally, a surfactant.

10 32.- The suspension of fenofibrate according to claim 31, in which the fenofibrate concentration is from 1 to 40% by weight.

15 33.- The suspension of fenofibrate according to claim 31, in which the hydrophilic polymer concentration is from 5 to 40% by weight.

20 34.- The suspension of fenofibrate according to claim 31, in which the surfactant is present at a concentration below 5% by weight.

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